

REMARKS/ARGUMENTS

Claims 1-5, 7, 9-13, 15 and 21-23 remain pending in the application. Applicant submits that the claims are in condition for allowance. Applicant requests reconsideration of the claims in view of the amendment presented above and the remarks presented below.

Rejections

Claims 1-5, 7, 9-13, 15, and 21-23 stand rejected under 35 U.S.C. § 103(a) as being obvious based on three combinations of references: (1) US 4,231,369 (US '369) in view of US 5,429,628 (US '628); (2) US 4,367,732 (,732) in view of US '628; and (3) WO 99114282 (WO '282) in view of US '628. Claims 22 and 23 also stand rejected under 35 U.S.C. § 103(a) as being obvious based on three combinations of references: (1) US '369 in view of US 5,714,445 (US '445); (2) US '732 in view of US '445; and (3) WO '282 in view of US '445.

Rejection Under 35 USC § 103

Claims 1-5, 7, 9-13, 15, and 21-23 stand rejected under 35 U.S.C. § 103(a) as being obvious based on three combinations of references: (1) US 4,231,369 (US '369) in view of US 5,429,628 (US '628); (2) US 4,367,732 (,732) in view of US '628; and (3) WO 99114282 (WO '282) in view of US '628. Claims 22 and 23 also stand rejected under 35 U.S.C. § 103(a) as being obvious based on three combinations of references: (1) US '369 in view of US 5,714,445 (US '445); (2) US '732 in view of US '445; and (3) WO '282 in view of US '445.

There are two independent claims pending. Claim 1 recites:

A pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of an uncomplexed hydrocolloid composition comprising a cyclodextrin and a hydrocolloid other than cyclodextrin.

Claim 22 recites:

A pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of a hydrocolloid composition consisting essentially of a cyclodextrin and a hydrocolloid other than cyclodextrin.

A. The Examiner Has Not Presented a Prima Facie Case of Obviousness

The Examiner continues to assert that it would have been obvious to combine US '628 or US '445 with each of the primary references, "motivated by the teaching ... that such an amount of uncomplexed cyclodextrin minimizes odor caused from body fluid, with reasonable expectation of having adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising uncomplexed cyclodextrin that effectively provides minimal odor from the body fluids." (OA, p. 4; similar statements are made with respect to the other rejections). That's merely a conclusion, not a detailed explanation; hence, the rejections are improper. See *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). The mere fact that cyclodextrin absorbs odor in some context doesn't provided a basis for combining US '628 or US '445 with the primary references. There is simple no teaching provided by the Examiner that cyclodextrin would function as an odor absorption agent when incorporated into an adhesive, muchless a hydrocolloid-type adhesive.

As stated in the previous responses submitted by Applicant, cyclodextrin is not a typical hydrocolloid and ***had never previously been proposed for use in hydrocolloid-type adhesives in the thirty five years that such adhesives had been known prior to the priority date of the present application.*** (Declaration of Roger Lipman, Ph.D. submitted with Applicant's RCE filed September 3, 2004 (hereafter, "Lipman Decl. "), ¶18). This is despite the fact that cyclodextrins have been known since the end of the nineteenth century. *Id.* US'369, US'732, and WO'282 list large numbers of hydrocolloids for possible use, but never mention cyclodextrins. Nor do those references suggests a need for or an advantage to be had by adding an odor-absorbent component to the adhesive itself. The problem addressed by US '369 was making a seal between a stoma device and a patient's torso in order to prevent material collected in the device from leaking, and to prevent it from coming in contact with the patient's skin. (US '369, 2:10-17). The problem addressed by US '732 was providing a skin barrier that is usable around moving body parts, and that provides seals around body openings. ('732, 1:9-17). The

problem addressed by WO '282 was developing hydrocolloid adhesives with higher absorption capacity and flexibility around movable body parts. (WO '282, p. 1, paragraph 2).

In US '628 and US '445, odor-absorbency is imparted to a diaper, panty liner, or similar object by providing cyclodextrin microparticles on the surfaces of the fibrous matrices of the absorbent articles. This would give no reason to suppose that cyclodextrin would exhibit such odor-absorbent properties when forming, in combination with another hydrocolloid, the discontinuous phase of a rubber-based adhesive composition.

B. The Objective Evidence of Nonobviousness Presented by the Applicant Rebutts the Examiner's Conclusion that the Claims are Obvious.

As previously submitted, Dr. Lipman has worked continuously with pressure-sensitive adhesives since 1965, and with hydrocolloids for over 25 years. Over the course of his professional career, Dr. Lipman has observed a long-felt need for an improved hydrocolloid-containing PSA, particularly an odor-absorbent PSA. (Lipman Decl., ¶¶ 7-9). The Examiner erred by ignoring this evidence. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) ("Evidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness").

Applicant also presented evidence of an unexpected synergy that results when cyclodextrin and a second hydrocolloid are used in combination in a PSA of the sort now claimed. (Lipman Decl. ¶¶ 10-13). The striking improvement in odor absorption achieved by the invention is demonstrated in the application as filed and in Dr. Lipman's declaration. In the application, at pages 30-33, an experiment is described in which hydrocolloid adhesive pads were inoculated with butyric acid. **Adhesives containing two or more hydrocolloids, at least one of which is a cyclodextrin (Examples 11 and 12) absorbed the butyric acid, and little or no odor was detected. Adhesives containing no cyclodextrin retained the strong odor of butyric acid after 24 hours.** Dr. Lipman describes a second experiment, with data presented as Exhibit C, that shows that a hydrocolloid PSA ("4-108A") containing cyclodextrin and a second hydrocolloid (sodium carboxymethyl cellulose) is a very effective odor absorbent. Water activates the cyclodextrin and greatly enhances the odor-absorbency of the PSA. (Lipman Decl. ¶ 12).

Dr. Lipman discovered that the claimed combination of cyclodextrin with another hydrocolloid in a PSA yields two unexpected advantages. First, when combined with another hydrocolloid, the cyclodextrin component exhibits strong odor-absorbing properties. It does not, however, exhibit such

properties when combined with a rubbery continuous phase as the sole hydrocolloid, as evidenced by the tests submitted with Dr. Lipman's declaration. As can be seen from example 4 of the application, combining 50% cyclodextrin and 50% polyisobutylene, and no additional hydrocolloid, exhibits static absorption of only $177\text{g/m}^2/24^{\text{h}}$, as opposed to over $7,000\text{g/m}^2/24^{\text{h}}$ exhibited by examples 1-3, in which other hydro colloids are used in addition to, or instead of cyclodextrin. Such low static absorption would mean that insufficient water was absorbed into the composition to activate the odor-absorbing properties of the cyclodextrin.

Second, cyclodextrin unexpectedly enhances the adhesive properties and integrity of the composition. Thus, compared to example 1, which uses three hydrocolloids but no cyclodextrin, example 2 had substantially increased reverse tack and integrity, while maintaining comparable peel adhesion and static absorption. Example 3 had substantially increased peel adhesion and reverse tack, while retaining comparable integrity and static absorption. ***As compared to example 6, examples 7 and 8, which illustrate the invention, had enhanced peel and sheer adhesion as well as substantially increased integrity, while maintaining acceptable levels of static absorption and cold flow.***

Applicants are now submitting a further unexpected advantage to products being currently used in the cronic wound dressing market which had not been realized or expected prior to the present invention.

Patients in the community, and in institutional settings such as hospitals and nursing homes, often have or acquire chronic wounds such as venostasis and decubitus ulcers, and these wounds can possess a very offensive odor. The most direct way of avoiding or eliminating the wound odor from these chronic wounds is to prevent or eradicate the bacteria responsible for it. Topical antibiotics such as metronitazole gel (0.8w/v) have proved to be quite effective, but can cause sensitisation and can generate resistant organisms. Further, the action of metronitazole can be sluggish; often several days are needed for any infection to be resolved, and meanwhile the odor is still being generated. Thus in practice other methods such as charcoal based dressings are often used, with or without concomitant antibiotic therapy.

Odor absorbing dressings have been marketed in one form or other for many years. During the past decades a number of charcoal based dressings have been introduced into the market. Some of the products are Actisorb[®] Silver (Johnson & Johnson), CarboFlex[®] (ConvaTec, a Bristol-Myers Squibb Company), Carbonet[®] (Smith and Nephew), and LyoFoam[®] C (SSL International). It was found by other workers that the proteins present in the serum exuded by chronic wounds greatly inhibited adsorption of odor by these charcoal dressings. Wound malodor obviously emanates in part from bacterial

decomposition of the proteins present in the serum, and the inhibition of charcoal odor absorbency by the odor precursor is a drawback to its use.

Clearly, the propensity of charcoal to lose effectiveness in the presence of wound exudates is a serious limitation. Charcoal is also of course black and nonconformable. Neither attribute is optimal for construction of wound dressings, which ideally should be self-adhesive, conformable, able to contact the wound surface, and not adversely affected by the presence of bacteria.

In accordance with the present invention, it has been surprisingly found that the combination of rubbers, hydrocolloids and uncomplexed cyclodextrin to form the odor absorbing, fluid absorbing adhesives that are the subject of the present invention yields a crucial and wholly unexpected advantage with respect to charcoal based odor absorbing adhesives, which latter quickly can become deactivated by the proteins always present in wound exudate. **The compositions of the present invention do not fluid become inactivated by the exudates of the wound.** On the contrary, the data say that the absorption of odor is at least the same in the presence of proteins. This is completely unexpected and not alluded to in any way by the prior art. A summary of the data that were obtained at the time the supporting work was completed in about 2003-4 is attached herewith. Table 3 of the attachment gives data showing the benefit of the present invention in absorbing odor in the presence of new born calves serum, a surrogate for wound serum.

The Examiner continues to assert that Dr. Lipman does not address the individual claims of the application and that the presented "objective evidence of nonobviousness is not commensurate in scope with the claims because the claims are directed to composition, and not method of its use as odor absorbent. See MPEP." This position of the Examiner, as previously submitted, ignores the law that a chemical invention includes its properties. See *In re Papesch*, 315 F.2d 381,391,137 USPQ 43, 51 (C.C.P.A. 1963) ("From the standpoint of patent law, a compound and all of its properties are inseparable; they are one .and the same thing"). Courts have historically "determined the unobviousness and patentability of new chemical compounds by taking into consideration their biological or pharmacological properties." *Id.* See also *In re Schreiber*, 128 F.3d 1473, 1481, 44 USPQ2d 1429, 1435 (Fed. Cir. 1997) (Newman, J., dissenting) ("The advantages of an invention are often relied on to support patentability; whether they are included in the claim depends on a variety of factors, and is not the subject of a rigid rule").

Moreover, there is simply no teaching suggestion or motivation found in the cited prior art which would lead a person of ordinary skill in the art to expect that an uncomplexed cyclodextrin would function in an odor absorption capacity when incorporated into a pressure sensitive adhesive. This is

merely an unsupported conclusory position asserted by the Examiner based on the teaching of the Applicant's own disclosure and not on what is taught or suggested by the cited prior art teachings.

Both the application as filed, Dr. Lipman's declaration and the further submission of unexpected properties of the present invention present compelling evidence that the claimed invention is not obvious. Reconsideration of the rejections is respectfully requested.

Conclusion

In view of the above, Applicant submits that the application is in condition for allowability. Withdrawal of the outstanding rejections and early notification of allowability is earnestly solicited. Should any issues remain, the Examiner is encouraged to contact the undersigned by phone to attempt to resolve any such issues.

If there are any fees associated with this communication, please charge said fees to Avery Dennison's Deposit Account No. 013025.

Respectfully submitted,
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